action, BSC asserted that a "curvy, offset" connector is the point of novelty of claim 36. D.I. 407, C.A. No. 03-027-SLR, at 25 ("Claim 36, as properly construed, is directed to a stent having curvy, offset connectors" (emphasis in original)).

Indeed, in the 03-027 action, BSC more broadly described "the invention claimed in '021 patent – the curvy, offset connector." D.I. 407, C.A. No. 03-027-SLR, at 24. And in his deposition in this case, Dr. Jang described his contribution to stent art as having a three-part connector ("curvy") with offset ends (Ex. D at Tr. 357:7-12):

> Q. So if I understand what you just said, it's your belief that your contribution to stent design is an offset connecter having offset ends that has at least three sections that can be straight or curved or -

#### A. Right.

BSC's description of "curvy, offset" connectors as the point of novelty for claims 35 and 36 is plainly driven by the fact – admitted by Dr. Jang – that horizontal curvy connectors were "old art."

## 7. Claim 35 Does Not Require "Curvy, Offset" Connectors Under the Approach Followed by Both Sides' Experts (and is Unlike Claim 36 in this Respect)

There is nonetheless an important difference between claim 35 and claim 36. As a result of the first-corner-to-second-corner connection that it requires, claim 35, in its most typical embodiment, describes a stent with a horizontal connector. This is the way both parties' experts analyze the claim. In contrast, the connector of claim 36 is different. It runs from the second-corner-to-first-corner. For these reasons, Conor moves for summary judgment on claim 35.

Independent claim 23, from which claim 35 depends, describes a stent composed of two expansion columns, both consisting of pairs of expansion struts connected on their

proximal side. That is, all of the strut pairs of claim 23 are connected on the same side. In its most natural reading, this describes a stent with an in-phase orientation.

The Jang '021 patent is replete with disclosures of such in-phase designs. Indeed, most of Jang's embodiments have an in-phase orientation. Thus, Figs. 1A, 2A, 2B, 3A, 3B, 4A, 4B, 5, 6A, 6B, 7A, and 7B of the '021 patent all depict stents that have an in-phase design. Moreover, all of the figures of Jang's provisional application (which the '021 specification incorporates by reference) show in-phase designs. And Dr. Moore has agreed that "most of the designs" in the '021 patent are "in-phase." D.I. 388 in C.A. No. 03-027-SLR at Tr. 1109:16 to 1110:1.

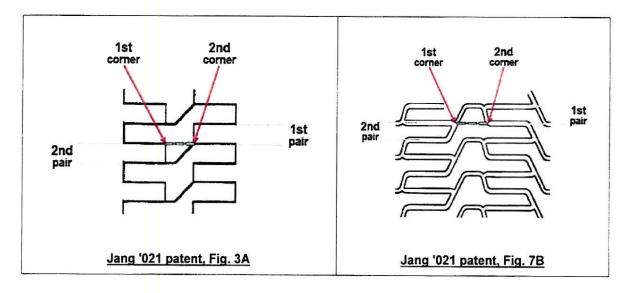
In an in-phase design, the first (upper) corner of the second expansion strut pair in the first expansion column is always aligned with the second (lower) corner of the first expansion strut pair in the second expansion column. Because those are the points at which the connection must occur for claim 35 - but not for claim 36 - the connector of claim 35 will always be horizontal in an in-phase design, like those that Jang preferred.

While the '021 specification includes many figures depicting in-phase designs, it does not include any figures depicting a stent with the upper-corner-to-lower-corner connection that is required by claim 35. Nor is that connection scheme described anywhere in the text of the '021 specification. Indeed, the only disclosure in the '021 patent of claim 35's upper-corner-tolower-corner connection appears in the text of claim 35 itself.

If Dr. Jang had actually undertaken to create a figure illustrating the use of claim 35's upper-corner-to-lower-corner connection with any of his in-phase designs, he (and the Examiner) both would immediately have recognized that using claim 35's upper-corner-to-lowercorner connector for an in-phase stent inevitably results in horizontal connectors whose end

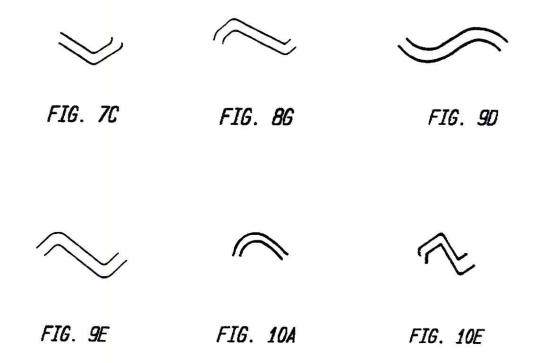
points are aligned on a line parallel to the stent's longitudinal axis – the same horizontal connector design that Dr. Jang described as "old art."

As shown below, for any one of Jang's preferred in-phase designs, the first (upper) corner of the second pair of the first expansion column is directly opposite the second (lower) corner of the first pair in the second expansion column:

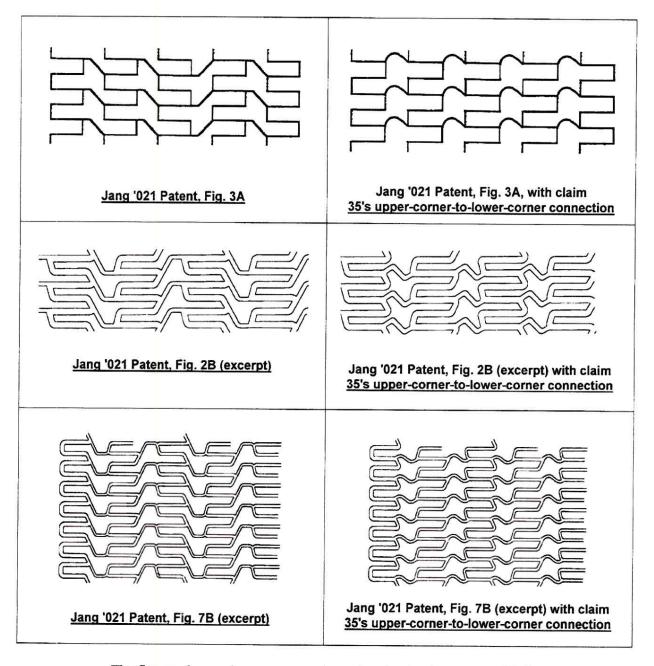


The undisputed fact is that a horizontal connection is inevitable with any in-phase embodiment of a stent with claim 35's upper-corner-to-lower corner connection. This is true regardless of whether the particular connector chosen is a straight bar (as was known in the prior art) or is a curvy connector (as also was known in the prior art). This horizontal connection necessarily results in any in-phase stent with a connector that is connected on its proximal end to the "first corner of the second expansion strut pair of the first expansion strut column" and connected on its distal end to the "second corner of the first expansion strut pair of the second expansion strut column," as recited in claim 35. '021 patent at 22:31-36.

Jang discloses a variety of multi-part (curvy) connecting struts that can be used with his invention. Some are shown below.



Using Jang's connecting struts and his in-phase designs, the following are embodiments of his claim 35. All have horizontal connectors.



The figures shown above are examples only. Any in-phase stent with the upper-corner-to-lower-corner (or first-corner-to-second-corner) connection required by claim 35 will have what Dr. Jang described as the "old art" design of horizontally oriented connectors. This is true for all of the in-phase designs preferred in the '021 patent and it is equally true for all other

in-phase designs. All of these in-phase designs are within the scope of claim 35, yet all of them have the "old art" of horizontal curvy connectors.

BSC does not and cannot dispute that claim 35 is broad enough to cover in-phase designs with the "old art" of horizontal curvy connectors. This undisputed fact refutes BSC's assertion that the "curvy, offset" connector is the point of novelty of claims 35. "Curvy, offset" connectors cannot be the point of novelty of claim 35 when that claim as drafted covers stents whose connectors are horizontally oriented rather than offset.

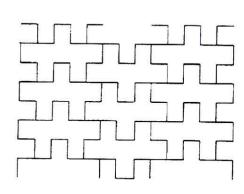
Moreover, this is true *regardless* of whether one applies the approach that BSC's expert uses or the different approach that Conor's experts use for numbering the "expansion struts" and "expansion strut pairs" for purposes of applying independent claim 23 (from which claim 35 depends). Under the approach followed by Conor's experts for applying claim 23, the "first expansion struts" in the first and second "expansion columns" of in-phase and 180 degree out-of-phase stents are positioned on the same level, <u>i.e.</u>, are collinear with each other. Under the different approach that BSC's expert uses in applying claim 23, the "first expansion strut pair" in the second expansion column (wherever it is) is the expansion strut pair that is connected to the "second expansion strut pair" in the first expansion column. Although the two sides' experts take differing approaches to the application of independent claim 23, the undisputed fact is that under *both* sides' approaches claim 35 covers stent designs with horizontally oriented connectors.

The in-phase designs shown above – of stents with claim 35's "upper-corner-to-lower-corner" resulting in horizontal connectors – are themselves not novel. Rather, they are in-phase versions of designs that already were known in the prior art.

As discussed above, one well-known prior art design with horizontal connectors was the Israel '303 patent (Ex. C), whose commercial embodiment was BSC's own NIR stent. Fig. 7 of Israel '303 depicts a design closely similar to what became the NIR stent. (The main design difference between the NIR and the stent shown in Fig. 7 is that the NIR has only "U" shaped connectors whereas Fig. 7 has both "U" shaped connectors and inverted "U" shaped connectors.) Fig. 6 of



Israel '303, Fig. 7



Israel '303, Fig. 6

Israel '303 is a schematic drawing of the same design. In both Figs. 6 and 7, the end points of the connectors are on a lie parallel to the stent's longitudinal axis.

The design of Israel '303 is particularly of interest because its horizontal multipart (curvy) connector was found to be obvious as of 1994. The '303 patent's priority date is 1994, two years before Jang's work. Yet, even at the time of the '303 patent in 1994, it was well known in the stent art that stents could be created from expansion columns that were connected together with curvy horizontal connectors. The '303 patent claim 12 was asserted in an earlier action in this Court. The claim was construed by this Court to require a horizontal connector, one that "must be aligned along the longitudinal axis of the stent." (Ex. P at A51). After trial, a jury in this Court found claim 12 of the '303 patent to be obvious. This Court denied JMOL, and the Federal Circuit affirmed. Scimed Life Sys., Inc. v. Johnson & Johnson, 225 F. Supp. 2d 422, 439-41 (D. Del. 2002), affd, 87 Fed. Appx. 729 (Fed. Cir. 2004).

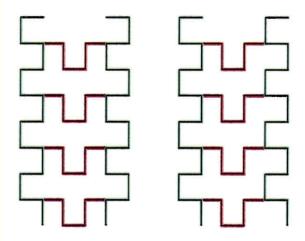
The curvy horizontal connector of Israel '303 was obvious in 1994. It is thus no wonder that BSC does not attempt to defend Jang's 1996 invention as a curvy horizontal connector – even though that is exactly what he has claimed.

Figs. 6 and 7 of the Israel '303 patent depict stents with a 180 degree out-of-phase design, but in-phase designs were a well-known design option and alternative as of 1996. As noted above, Cordis' engineering expert Dr. Ron Solar stated in his expert report on validity "by 1996, the choice of in-phase rings, out-of-phase rings, or rings somewhere in between ... was a routine design choice." Ex. F at 10. In his rebuttal report, Prof. Moore agreed that "stents with in-phase and out-of-phase designs were known in the art in 1996." Ex. I, at ¶ 18.

An in-phase version of the 180 degree out-of-phase design shown in Figs. 6 and 7 of Israel '303 would have horizontal connectors – and would be squarely covered by claim 35 of the Jang '021 patent. Once again, this is merely the inevitable consequence of using an in-phase design (which Jang preferred in most of his disclosed embodiments) and the "top-corner-to-bottom-corner" connection required by claim 35.

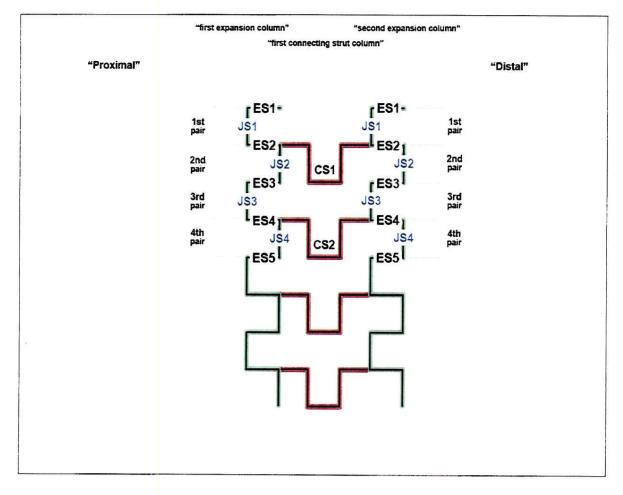
Cordis' expert Dr. Buller pointed this out in his opening expert report in this case on the invalidity of claim 35. In his opening expert report, served on March 19, 2007, Dr. Buller explained in detail that an in-phase version of the design shown in Fig. 6 of the Israel '303 patent would satisfy all of the limitations of claim 35 and would have connectors with end points that are horizontally aligned. Ex. G at 31-32 and Ex. C to the Buller report. To illustrate this point, Dr. Buller included in his report the two images that appear below. He explained that "[t]he image on the left is Figure 6 of the Israel '303. The image on the right is the same image, except that the second expansion column is inverted from its original position (so as to now be in-phase

with the first expansion column). (The expansion columns are highlighted in green; the connector columns are highlighted in red.)." <u>Id.</u> at 31.



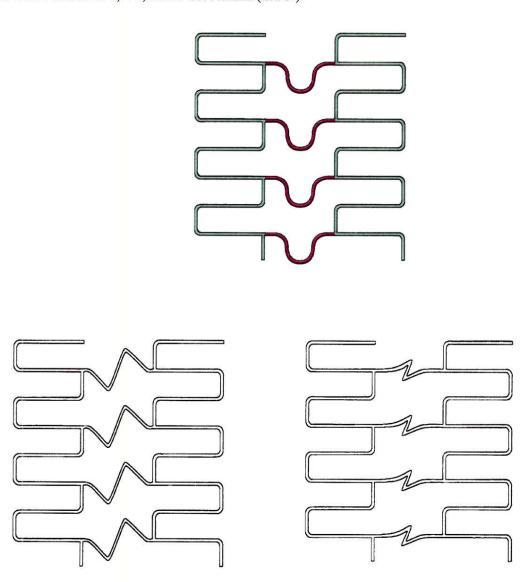
As Dr. Buller further explained, claim 35 of the '021 patent reads directly on the in-phase design version of Israel '303 that is shown on the right above. <u>Id</u>. This is true <u>both</u> when one uses the approach taken by BSC's expert or the approach taken by Dr. Buller for numbering the "expansion struts" and "expansion strut pairs" for purposes of independent claim 23 (from which claim 35 depends). <u>Id</u>.

In addition, Dr. Buller included the following schematic drawing in his report as Exhibit C to depict exactly how claim 35 covers this design. In this drawing, the designation "ES1" refers to the first "expansion strut"; "JS1" refers to the first joining strut; and "CS1" refers to the first "connecting strut":



As Dr. Buller explained in his report, this in-phase version of Fig. 6 of Israel '303 satisfies all of the limitations of claim 35 of the '021 patent. Ex. G at 32. Thus, as shown above, the first connecting strut (CS1) is coupled on its proximal end to the "first corner [upper] of the second expansion strut pair of the first expansion column" and coupled on its distal end to the "second [lower] corner of the first expansion strut pair of the second expansion column," exactly as required by claim 35. Likewise, the second connecting strut (CS2) is coupled on its proximal end to the "first [upper] corner of the fourth expansion strut pair of the first expansion column" and coupled on its distal end to the "second [lower] corner of the third expansion strut pair of the second expansion column," again, exactly as required by claim 35. This design, with its horizontal connectors, is thus squarely within the scope of claim 35. Id. at 31-32.

Indeed, as discussed above, *all* in-phase designs that have the "upper-corner-to-lower corner" connection pattern recited in claim 35 will inevitably have the horizontal connectors that Dr. Jang described as "old art." Three alternate embodiments of an "in-phase" design are shown below, with the "top-corner-to-bottom-corner" connection of claim 35 and connectors available in 1996 from the Israel '303 patent (Ex. C), Pinchasik '373 patent (Ex. K), and U.S. Patent No. 5,776,161 to Globerman (Ex. N):



As discussed above, in-phase designs were a well-known design alternative by 1996. As Dr. Buller stated in his expert report, the fact that claim 35 covers in-phase designs with horizontal connectors makes it "inaccurate" to assert - as BSC asserts - that claim 35 "requires 'curvy, offset connectors." Ex. G at 32. Rather, as Dr. Buller stated "the language of claim 35 is so broad that it ... reads on designs with wavy connectors whose ends are co-linear," id. at 29, such as the in-phase designs shown above.

Making in-phase stents like those shown above was an obvious design choice in 1996. These stents are in-phase versions of the stent depicted Fig. 6 of the Israel '303 patent. As Cordis' engineering expert Dr. Ron Solar stated in his report and as BSC's expert concedes, inphase and 180 degree out-of-phase designs were well-known design choices by 1996. Ex. F at 10; Ex. I at ¶ 18. Moreover, as Dr. Buller explained in his report, various prior art references specifically encouraged persons of skill in the art to "mix and match" the known elements of stent design. Ex. G at 19.

## 8. BSC's Expert Did Not Dispute - and Cannot Dispute - that Claim 35 as Drafted Covers Stents With the "Old Art" of Horizontal Connectors

On April 12, 2007, BSC served a rebuttal expert report from Prof. Moore in response to Dr. Buller's report on invalidity. In his rebuttal report, Prof. Moore had the opportunity to respond to Dr. Buller's opinions on obviousness, including his stated opinion that claim 35 of the '021 patent would read directly on the in-phase version of Fig. 6 of the Israel '303 patent with horizontal connectors that is shown above. If Dr. Moore had any intention of disputing Dr. Buller's opinions on the subject, his rebuttal expert report was the time and place for him to set forth "all opinions to be expressed and the basis and reasons therefor." Fed. R. Civ. P. 26(a)(2)(B); see also Vandenbraak v. Alfieri, 2005 WL 1242158, at \*3 (D. Del.

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May 25, 2005) (the purpose of Rule 26(a)(2)(b) is "to protect opposing parties from unfair surprise").

In his rebuttal report, Prof. Moore did not disagree with Dr. Buller's opinion on this subject. In particular, he did not disagree with Dr. Buller's opinion that claim 35 of the '021 patent would cover the in-phase version of the Israel '303 Fig. 6 design, with connectors whose end points are horizontally aligned rather than offset.

Prof. Moore was also asked about this issue in his deposition. Again, he did not dispute Dr. Buller's opinions. Instead, he conceded that "it's possible" claim 35 covers this design. He then tried to dodge the issue by stating that he not considered the issue, even though it was squarely presented by Dr. Buller's opening report on validity (Ex. L at 93:15-94:10):

> Would you agree that this design satisfies all the limitations of claim thirty-five of the '021 patent?

[BSC's counsel]: Objection. Assumes a fact not in evidence.

A. Again, I'm not - I haven't analyzed this drawing in that regard. I haven't considered that carefully. It's not a relevant drawing with regard to the Israel '303 patent, because the Israel '303 patent teaches away from designs like this. And since claim thirty-five depends on claim twenty-three, I'm not sure what I can say further other than it's possible but I'm not prepared to give a definitive answer on that today.

The deposition was the time and place for Prof. Moore to explain his opinions on this and other subjects - not to dodge the issue in hopes of presenting previously undisclosed opinions at trial.

Prof. Moore's inability to dispute Dr. Buller's stated opinions on this subject leaves Dr. Buller's opinion undisputed. Thus, there is no dispute that claim 35 covers in-phase designs with the "old art" of horizontal connectors, as shown in the in-phase version of the Israel

'303 patent, Fig. 6. What BSC describes as the point of novelty of claim 35, in fact, is not required by that claim.

## ARGUMENT

# THIS COURT SHOULD GRANT SUMMARY JUDGMENT THAT CLAIM 35 IS OBVIOUS AS A MATTER OF LAW

#### A. The Standard for Summary Judgment

Summary judgment should be granted where "there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter law." Oney v. Ratliff, 182 F.3d 893, 895 (Fed. Cir. 1999) (citing Fed. R. Civ. P. 56(c)). Because obviousness is a question of law premised on factual determinations, a district court should grant summary judgment on obviousness "when the underlying factual inquiries present no lingering genuine issues." Beckson Marine, Inc. v. NFM, Inc., 292 F.3d 718, 723 (Fed. Cir. 2002).

A primary purpose of summary judgment is eliminating factually unsupported claims. Fed. R. Civ. P. 56(e). Thus, to defeat summary judgment on obviousness, the nonmovant must point to "specific facts" concerning the "scope and content of the prior art" in relation to the "claims at issue" that would allow a trier of fact to find in its favor. See Avia Group Int'l, Inc. v. L.A. Gear Calif., Inc., 853 F.2d 1557, 1564 (Fed. Cir. 1988) (citing Graham v. John Deere Co., 383 U.S. 1, 17 (1966)).

#### B. The Supreme Court's Recent Decision in the KSR Case

The Supreme Court recently clarified the standards that govern an obviousness analysis. In KSR International Co. v. Teleflex, Inc., 550 U.S. , 127 S. Ct. 1727, 82 U.S.P.Q.2d at 1395 (2007), the Court rejected a "rigid approach" to analyzing obviousness, and held that under Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966), and its progeny, "[t]he

combination of familiar elements according to known methods is likely to be obvious when it does no more than yield *predictable results*." KSR, 82 U.S.P.O.2d at 1395 (emphasis added).

The Supreme Court then stated (id. at 1396):

If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. Sakraida and Anderson's-Black Rock are illustrative - a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. (Emphasis added).

The Supreme Court also stated (id. at 1397):

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103. (Emphasis added).

See also id. at 1396 ("[T]he analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.").

KSR also clarified the principles that govern motions for summary judgment on obviousness. The Court of Appeals had held in KSR that summary judgment of obviousness was inappropriate in that case because experts disagreed on that issue. The Supreme Court rejected that approach and found that the Court of Appeals "misunderstood the role expert testimony plays in the analysis." Id. at 1400. It held that "[t]he ultimate judgment of obviousness is a legal determination." Id. Accordingly, "summary judgment is appropriate" on obviousness where "the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art

are not in material dispute, and the obviousness of the claim is apparent in light of these factors." Id. The Supreme Court emphasized that an expert's "conclusory affidavit addressing the question of obviousness" cannot defeat a motion for summary judgment. Id.

#### C. Claim 35 is Obvious Under KSR

The principles outlined in KSR require a finding of obviousness in this case. Indeed, those principles apply with particular force in cases such as this, involving mechanical arts where interchanging known alternatives will yield predictable results. Cf. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., F.3d \_\_\_\_, 2007 WL 1345333, at \*4 (Fed. Cir. May 9, 2007) (applying KSR and affirming summary judgment of obviousness) ("Accommodating a prior art mechanical device ... to modern electronics would have been reasonably obvious to one of ordinary skill in designing children's learning devices").

There is no material dispute here as to the content of the prior art, the scope of claim 35 and the level of ordinary skill in the art.3 Moreover, as discussed above, Fig. 6 of the Israel '303 depicts a 180 out-of-phase design with the "old art" of horizontally oriented, curved connectors. In the "crowded field" of stent design [cite]. An in-phase version of that design which is covered by claim 35 of the '021 patent – was a "predictable variation," KSR, 82 U.S.P.Q.2d at 1396, which "a person of ordinary skill can implement." Id. As the Supreme

<sup>&</sup>lt;sup>3</sup> Although the parties' experts describe the person of ordinary skill in somewhat different terms, any such differences are not material and have no bearing on the obviousness analysis. BSC's expert Prof. Moore states that the "[I]f limited to a single person, as opposed to a team, a person of ordinary skill in the art as of April 26, 1996 would have been: (i) a physician specializing in radiology, cardiology, cardiovascular surgery or some related discipline, with perhaps training, experience and/or familiarity applying principles of mechanical or biomedical engineering or material science; or (ii) an engineer having at least a bachelor's degree in mechanical or biomedical engineering or materials science with experience in the design of, and requirements for, implantable medical devices." Ex. H at 4. Conor's expert Dr. Buller uses a slightly different formulation. See Ex. G at 6-7 ("A person of ordinary skill in the art in the 1996 to 1997 time frame would have been a physician practicing in the field of treating occlusive vascular disease. working in combination with an engineer who had at least a bachelor's degree in mechanical or biomedical engineering or materials science and at least 5 years experience in the design of medical devices for implantation in the body.").

Court stated in KSR, "§ 103 likely bars [the] patentability" of this kind of "predictable variation" of a known design. Id.

Creating an in-phase version of the 180 degree out-of-phase design, such as depicted in Fig. 6 of the Israel '303 patent, would have been obvious to one of ordinary skill in the art. As Cordis' engineering expert Dr. Ron Solar stated in his expert report, in-phase and 180 degree out-of-phase expansion columns both were well-known by 1996. Ex. F at 10. BSC's expert Prof. Moore agreed that "stents with in-phase and out-of-phase designs were known in the art in 1996." Ex. I at ¶ 18. As Dr. Solar opined – without disagreement from BSC's expert – the choice between these known design alternatives was merely "a routine design choice exercised by engineers." Ex. F at 10. Moreover, BSC has not presented any evidence that creating an inphase version of a known design such as Fig. 6 of the Israel '303 patent "was uniquely challenging or difficult for one of ordinary skill in the art." Leapfrog, 2007 WL 1345333 at \*5 (applying KSR and affirming summary judgment of obviousness). In short, an in-phase stent with a curvy horizontal connector was the kind of "predictable variation" that warrants a finding of obviousness under KSR, 82 U.S.P.Q.2d at 1396.

Indeed, in-phase designs and 180 degrees out-of-phase designs were the primary alternatives in existing for the orientation of adjacent expansion columns. The stents that were commercially available and most well-known as of 1996 utilized one or another of these known alternatives. Indeed, most, if not all, commercially successful stent designs at that time were either in-phase (as in ACS's Multi-Link stent) or 180 degrees out-of-phase (as in AVE's MicroStent II and BSC's own NIR stent). Substituting an in-phase design for an out-of-phase design involved nothing more than "the predictable use of prior art elements according to their established functions." Id. at 1396. This kind of substitution of one known alternative for the

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other "is likely the product not of innovation but of ordinary skill and common sense." Id. at 1397.

An in-phase version of a stent such as Israel '303 is a "predictable use of prior art elements according to their established functions," Id. at 1396, that is squarely within the scope of claim 35 of the '303 patent. Conor's expert Dr. Buller explained this in detail in his expert report, with figures illustrating his analysis. BSC's expert Prof. Moore did not disagree. Thus, the fact that claim 35 covers this -phase version of Israel '303 is undisputed.

As the Supreme Court emphasized in KSR, Id. at 1397:

In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. (Emphasis added).

Here, it is undisputed that "the objective reach" of claim 35 encompasses stents - such as the inphase version of Israel '303 – in which the end points of the connector are horizontally aligned, rather than offset. Conor's expert Dr. Buller demonstrated in his expert report (Ex. G at 31-32 and Ex. C) that the "objective reach" of claim 35 encompasses stents with horizontal connectors, like the in-phase Israel design. Once again, BSC's expert did not disagree. This fact is thus undisputed.

These undisputed facts refute the assertion by BSC and its expert that claim 35 requires a "curvy, offset" connector. These same undisputed facts also refute BSC's assertion that a "curvy, offset" connector is the point of novelty of claim 35. The undisputed facts establish that the "objective reach" of claim 35 covers stents with horizontal connectors – precisely what Dr. Jang described as "old art." This kind of implementation of "old art" is obvious under § 103.

Moreover, as of 1996, persons skilled in the art had ample reason to try predicable variations of what was known, including an in-phase stents with multi-part (curvy) connectors. As the Supreme Court explained in KSR, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." <u>Id.</u> at 1397. As the Supreme Court further explained (id.):

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. (Emphasis added).

Here, the "design need" and "market pressure" to try identified known alternatives (id.) was particularly compelling. By 1996, balloon-expandable stents practicing Dr. Palmaz's pioneering inventions already were a huge commercial success. As Dr. Buller explained in his expert report - without contradiction from BSC - the success of Dr. Palmaz's pioneering work with balloon expandable stents, culminating in the U.S. launch of the Palmaz-Schatz stent in 1994, had led to a "frenzy of activity in the medical device industry." Ex. G at 18. This "frenzy of activity" was described in 1996 in an article Dr. Buller relied upon. See Ex. O at 886 (Ruygrok et al., From Bench to Bedside, Intracoronary Stenting From Concept to Custom, Circulation 1996: 882-90 (1996) (stating that a "frenzy of activity has pervaded the stent development industry").

This "frenzy of activity" provided the "market pressure" (KSR, at 1397) that would have given persons of ordinary skill "good reason to pursue the known options within his or her technical grasp." Id. As discussed above, those "known options" (id.) included the two basic alternatives for orientation of adjacent expansion columns, i.e., the choice of using an inphase design or a 180 degree out-of-phase design. Choosing an in-phase design was nothing more than a "predictable variation" (KSR, 82 U.S.P.Q.2d at 1396) on the 180 degree out-ofphase design that Israel '303 discloses. This kind of "predictable variation" (id.) between

"known options within [the] technical grasp" of a person of ordinary skill (id. at 1397) is obvious under § 103.

Moreover, as Dr. Buller explained in his report, the literature on stent design that existed as of 1996 "specifically encouraged stent designers to mix and match" the known elements of stent design. Ex. G at 19. Those known elements certainly included in-phase and 180 degree out-of-phase designs, and various types of connectors, including connectors (both straight and curvy) that were horizontally oriented (with their end points on a line parallel to the stent's longitudinal axis).

As the Supreme Court explained in KSR at 1400:

Where, as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors, summary judgment [of obviousness] is appropriate. (Emphasis added).

### D. Secondary Considerations Support the Ultimate "Legal Determination" of Obviousness

As discussed above, the frenzy of activity that pervaded the stent industry in the 1994-96 time frame would have given persons of ordinary skill a reason to make "predictable variation[s]" (Id. at 1396) utilizing "known options" (id. at 1397) of stent design. One "predictable variation" was an in-phase design with a three-part (curvy) connector. Doing so was well within the "technical grasp" of persons of ordinary skill in 1996.

Secondary considerations support the ultimate "legal determination" (Id. at 1400) that this predictable variation was an obvious alternative at the time (see generally, Ex. G at 49-51):

As to commercial success: BSC has never marketed a stent practicing claim 35 and cannot point to any stent practicing claim 35 that has been commercially successful. In

particular, it cannot show that an in-phase stent with horizontally aligned curvy connectors was ever marketed or commercially successful.

As to long-felt need: BSC cannot show, and has not tried to show, that there was any "long-felt need" for an in-phase stent with horizontally aligned curvy connectors.

As to failed attempts by others: BSC cannot show, and has not tried to show, that anyone who ever sought to create an in-phase stent with horizontally aligned connectors failed in his or her attempts to do so.

As to copying by others: There is no evidence that anyone ever copied the stent design disclosed in claim 35 of the '021 patent.

As to initial skepticism: There is no evidence that the stent or claim 35 was met with skepticism or, more particularly, that anyone ever expressed skepticism about an in-phase stent with horizontally aligned connectors.

As to praise for the invention: There is no evidence of praise for the claim 35 invention.

# **CONCLUSION**

For the reasons set forth above, this Court should grant Conor's motion for summary judgment of obviousness of claim 35 of the Jang '021 patent.

# ASHBY & GEDDES

/s/ Lauren E. Maguire

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# **CERTIFICATE OF SERVICE**

I hereby certify that on the 18<sup>th</sup> day of May, 2007, the attached REDACTED PUBLIC VERSION OF OPENING BRIEF IN SUPPORT OF CONOR MEDSYSTEMS' MOTION FOR SUMMARY JUDGMENT OF OBVIOUSNESS OF CLAIM 35 OF THE JANG '021 PATENT was served upon the below-named counsel of record at the address and in the manner indicated:

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VIA FEDERAL EXPRESS

/s/ Lauren E. Maguire

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